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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,725	11/03/2000	Andreas Tauch	P 274355 990111BT-PAT	7227

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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/704,725

Applicant(s)

TAUCH ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6 and 13-32 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 30-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17,19,20,27,29 is/are allowed.
- 6) ☒ Claim(s) 2,3,5,6,13-16,18,21-26 and 28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants submission of a new declaration, amendment of claims 2, 3, 5 and 6, cancellation of claims 4, 7 and 8 without prejudice and the addition of claims 13-32, Paper Nos. 14 and 15, 10/4/2002, is acknowledged. Claims 1-3, 5, 6, 13-32 are at issue and are present for examination.

Applicants' arguments filed on 10/4/2002, Paper No. 15, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Election/Restrictions

Newly submitted claims 30-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 30-32 are drawn to an isolated DNA encoding a tetracycline resistance protein, spectinomycin/streptomycin resistance protein or a tetracycline resistance repressor protein.

Inventions of originally elected group I and the invention of claims 30-32 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as

claimed because the claimed plasmids can use alternative antibiotic resistance regions. The subcombination has separate utility such as for encoding for antibiotic resistance and incorporation in different plasmids.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 30-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim 1 and 30-32 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Oath/Declaration

Applicants submission of a new declaration is acknowledged, however this declaration is also defective.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The residence listed for inventor Andreas Tauch is incorrectly listed as "Blefeld".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 5, 13, 15, 16, 22, 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (3, 5, 13 and 15 dependent from) is indefinite in that the recitation "active antibiotic resistance" is unclear. Specifically it is unclear how "active antibiotic resistance" is different from "antibiotic resistance" and what the term "active" adds to the claim.

Claim 16 is indefinite in that it is unclear in the recitation "constituents of plasmid pTET3". What are constituents of plasmid pTET3? Does this refer to parts of the plasmid that encode for functional proteins or are responsible for specific functions, or is a constituent as small as a few nucleotides?

Claim 26 and 28 are indefinite in that it is unclear what the "function of a stabilization protein" (claim 26) is as well as it is unclear what the "function of a replication protein" (claims 26 and 28) is.

Claim 22 is indefinite in that it recites the plasmid pTET3 of claim 30. There is no antecedent basis for the plasmid in claim 30, as claim 30 is drawn to an isolated DNA, not a plasmid. Further, as discussed above claim 30 is drawn to a nonelected invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 2, 3, 4, 5 and 6 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is hereby withdrawn.

The rejection was stated in the previous office action as it applied to previous claims 2-6. In response to this rejection, applicants cancelled claim 4, amended claims 2, 3, 5 and 6 and traversed the rejection as it applied to these newly amended claims.

Applicants submit that claims 2-6 are fully enabled by the specification and that the claims as amended are directed to a finite number of plasmids that are capable of autonomous replication in bacteria of the genus corynebacterium, wherein the plasmid comprises i) at least a portion of the nucleotide sequence of plasmid pTET3 or pCRY4, ii) at least one DNA replication region obtained from one of the plasmids pTET3 or pCRY4; and iii) at least one region that encodes a protein for active antibiotic resistance (See above 112 second paragraph rejection). Applicants are reminded that this is not a rejection based on a lack of adequate description but rather a lack of adequate written description. As both parts i) and iii) lack any structure the structure of the claimed plasmids are described based solely on part ii) at least one DNA replication region obtained from one of the plasmids pTET3 or pCRY4. As the replication region obtained from the plasmids pTET3 or pCRY4, Figures 3 and 4, are sufficiently described, the

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genus of plasmids comprising the DNA replication region obtained from one of the plasmids pTET3 or pCRY4 are adequately described.

Claims 2, 3, 5, 6, 13-16, 18, 21, 22, 23, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection was stated in the previous office action as it applied to previous claims 2-7. In response to this rejection, applicants cancelled claim 4, amended claims 2, 3, 5 and 6 and traversed the rejection as it applied to these newly amended claims.

Applicants filing of a declaration stating that the referred to plasmids have been deposited under the terms of the Budapest Treaty and the statement by an attorney of record over his or her signature and registration number, showing that: 1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request; 2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent; 3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and 4. the deposit will be replaced if it should ever become inviable is acknowledged however applicants declaration is not persuasive with respect to the plasmid pCRY4, because the declaration does not refer to the plasmid pCRY4, but rather pCRY4m.

Further it is noted that claims 22 and 25 refers to plasmids pGA3, pBL1 and pHM1519. Since the plasmids are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids. The specification does not disclose a repeatable process to obtain the plasmids and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;
2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
4. the deposit will be replaced if it should ever become inviable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
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March 21, 2003